(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 099 758**
A2

(12) EUROPEAN PATENT APPLICATION

(21) Application number: 83304203.9

(22) Date of filing: 20.07.83

(51) Int. Cl.³: A 61 F 13/00
A 61 L 15/00

(30) Priority: 21.07.82 GB 8221044

(43) Date of publication of application:
01.02.84 Bulletin 84/5

(84) Designated Contracting States:
AT BE CH DE FR GB IT LI LU NL SE

(71) Applicant: University of Strathclyde
McCance Building 16 Richmond Street
Glasgow, Scotland(GB)

(72) Inventor: Juhasz, Laszlo, Dr.
Kilmardinny Avenue Bearsden
Glasgow Scotland(GB)

(74) Representative: Huskisson, Frank Mackie et al,
FITZPATRICKS 4 West Regent Street
Glasgow G2 1RS Scotland(GB)

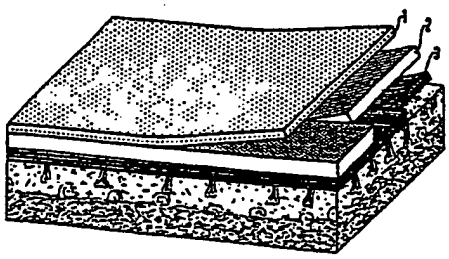
(54) Composite wound dressing.

(57) The multilayered composite wound dressing comprises of a semipermeable membrane, a permeable supporting and reinforcing layer, and a non-stick, self-sealing biodegradable tissue interface. The semipermeable membrane may be a synthetic collagen, an alginate or a biocompatible polymer and it controls the rate of water vapour transmission from the wound surface. The permeable supporting and reinforcing layer provides mechanical strength and is usually a textile fabric which may also be made electrically conductive by coating it with a carbon-doped silicon or natural rubber or depositing metal on the fabric. Alternatively, an activated carbon cloth fabric can also be used. The biodegradable tissue interface may be synthetic collagen, sodium-calcium alginate or collagen-alginate complex, and it provides non-stick haemostatic sealing and aids the wound repair processes. For topical medication, growth promoting, antibacterial, anti-allergic and therapeutic agents may also be incorporated.

Any combination of each of the materials suitable for a particular layer can be used for a specific application.

The conductive supporting and reinforcing layer can be used to provide electrical charge transfer and stimulation of the wound using external fields which has been shown to enhance the wound healing process, produce post-operative pain relief and bacterial-inhibition. The composite wound dressing has application inter alia in treating general surgical wounds, burns, bedsores, infected ulcers, donor sites for skin grafts or alternatively can be used for electrode dressing in transcutaneous and functional stimulation.

FIG. 1.



EP 0 099 758 A2

0099758

Composite Wound Dressing

The present invention relates to composite wound dressings and particularly, but not exclusively, for use as a general surgical wound dressing, burn dressing, donor site dressing, bedsore dressing, infected ulcer dressing and like applications. It may also be used as an electrode dressing for transcutaneous pain relief or functional stimulation.

In order for a composite wound dressing to be as effective and efficient as normal skin it must simulate the function of normal skin. There are three main requirements that normal skin fulfils; firstly it provides controlled water vapour permeability, secondly the skin provides a tough mechanical barrier between the tissues and the external enviroment with uniform pressure distribution and acts as a barrier to infection and thirdly, it provides a bioactive tissue interface to maintain an adaptive physiological performance and intracellular/extracellular activities in wound repair. It is therefore considered that a composite wound dressing should satisfy all of these basic requirements and take part in the fundamental activities of the wound healing process. The author considers that, at the present time, there is no composite wound dressing available which satisfies all these requirements.

It is an object of the present invention to obviate or to mitigate the disadvantages associated with current composite wound dressings.

According to the present invention there is provided a composite wound dressing comprising in a layered arrangement, a semipermeable membrane, a supporting and reinforcing permeable layer and a biodegradable tissue interface, said permeable layer being located between the semipermeable membrane and the biodegradable tissue interface.

Preferably also, the supporting and reinforcing permeable layer is electrically conductive.

Preferably said permeable layer is polyester, polyethylene or cotton fabric coated with carbon doped silicon or natural rubber. Alternatively, said fabrics are plated or deposited with metals such as silver, zinc, gold, platinum and the like.

Alternatively, said permeable layer is charcoal cloth fabric consisting of substantially 100% activated carbon, said cloth fabric being produced by carbonising and activating (700 - 1200)°C a woven viscose rayon fabric.

Preferably also, said biodegradable interface is a synthetic collagen produced from animal sources such as calf skin and intestines. Alternatively, the biodegradable tissue interface is a Na-Ca alginate produced from seaweeds. Preferably also, the said biodegradable tissue interface is a collagen-alginate complex with ratio of (0.1 - 30) and it is prepared as porous structure.

Preferably also, the semipermeable membrane is a synthetic collagen. Alternatively, the semipermeable membrane may be an alginate or a biocompatible polymer such as polyurethane, polypropylene, silicon rubber etc.

Embodiments of the present invention will now be described by way of example with reference to the accompanying drawings, in which:-

Fig. 1 is a schematic diagram of a composite wound dressing in accordance with the present invention, and

Fig. 2 is an alternative diagram of another composite wound dressing in accordance with the present invention;

Fig. 3 is a schematic diagram of a composite wound dressing for use on burns in accordance with the present invention;

Fig. 4 is a schematic diagram of a composite wound dressing for use of a general wound dressing without electrical stimulation, and

Fig. 5 is a schematic diagram of a composite wound dressing for use in providing transcutaneous pain relief and for

functional stimulation in accordance with the present invention.

Referring now to Fig. 1 of the drawings, the composite wound dressing comprises; a calcium alginate semipermeable membrane 1, an electrically conductive silverester fabric 2, and a biodegradable Na-Ca alginate (BdA) 3.

The biodegradable alginate is produced from brown seaweed (phaeophycae) which contains naturally occurring polysaccharides. The BdA is prepared by purifying and acidifying to a various degree the sodium alginate to obtain a slow dissolving material. In principle therefore BdA contains both sodium and calcium alginate with a ratio of (Na/Ca)=0.1 to 50.

The dressing is placed on a wound, for example a burn with the biodegradable alginate in contact with the wound surface. Once the BdA 3 is in contact with tissue fluid, i.e. such as exudate, it dissolves at a predetermined rate. In this hydrolysed state it produces a viscous polyelectrolyte film which provides haemostatic wound sealing an electrical charge transfer of the sodium and calcium ions from an external source. The multilayered design is similar in structure to normal skin and provides near physiological performance since the semipermeable membrane controls the rate of water vapour transmission from the tissue. The supporting fabric provides increased mechanical strength with uniform pressure and electrical field distribution and the biodegradable tissue interface 3 provides haemostatic sealing and influences when electrically energised intracellular and extracellular activities in the wound repair process.

With regard to the composite wound dressing as shown in Fig. 2 a polyurethane polymer 4 is the semipermeable membrane, the supporting fabric 5 is a cotton fabric coated with carbon-doped silicon or natural rubber, and the biodegradable tissue interface 6 is a synthetic collagen produced from calf skin or calf intestine or from other animal sources. After several stages of purification a collagen film or fabric is prepared and used. This composite wound dressing functions in a similar way to that described with reference

to Fig. 1, however, the carbon-doped silicon rubber is the electrically conductive reinforcing permeable layer.

An external electro-motive-force or magnetic field (both denoted as EMF) can influence both normal neurovascular processes and tissue repair mechanisms. The doping should not give preferably electrical resistance greater than 600 ohms/square unit since this necessitates providing a higher voltage to maintain a current within the tissue sufficient to provide EMF assisted wound healing. A typical example for current density is (1-10) A/cm^2.

With respect to neurovascular control, an externally applied EMF will induce localised vasoconstriction to re-establish the balanced osmotic feedback between the blood vessels and the neighbouring tissue. Thus the widened and damaged capillary bed, due to trauma induced histamine stimulation, will contract due to the applied EMF.

The protein concentration in the blood vessels will be maintained at a high level and consequently water will be drawn back into these vessels by osmosis. This re-establishment of osmotic feedback prevents the accumulation of both water and proteins in the surrounding tissue, thus reducing local pain and inflammation due to the fluid pressure on the sensory nerve endings.

Additionally, an externally applied EMF can accelerate the tissue regeneration aspect of healing by restoring order to the basic biological processes of all division and synthesis which give rise to the large numbers of phagocytes necessary for epithelialisation to proceed. Here the postulated mechanism is one of stabilisation of the normal cellular activities followed by an early acceleration of the cell synthesis required for tissue reconstruction.

Results showed that wounds treated with such a dressing and having external EMF's applied healed better and quicker than unstimulated wounds with minimum scar formation.

With regard to the wound dressing shown in Fig. 3 a polyurethane polymer 7 is the semipermeable membrane, the

supporting fabric is a charcoal cloth fabric 8 and a synthetic collagen-alginate 9 is the biodegradable tissue interface. This composite wound dressing can be connected to a source of electrical energy and is particularly suitable for treating burn wounds.

With regard to the composite wound dressing as shown in Fig. 4, a polyurethane polymer 10 is the semipermeable membrane and the biodegradable tissue interface is a collagen-alginate or (Na-Ca) alginate 11. This dressing is particularly suitable for use as a general surgical wound dressing without electrical stimulation.

With regard to the composite wound dressing shown in Fig. 5 a polyurethane polymer 12 is used as the semipermeable membrane and the supporting and reinforcing permeable layer is a charcoal cloth fabric 13. There is no biodegradable tissue interface and this wound dressing is used to provide transcutaneous pain relief and functional stimulation. This type of dressing is normally used with epithelialised wounds to enhance long-term collagen synthesis which will increase tissue strength and reduce scar formation or to cover free flaps to increase local blood supply.

Without departing from the scope of the invention it will be understood that different materials may be used in the manufacture of the composite wound dressing according to the invention. For example, the semipermeable membrane may be made of biodegradable materials such as a synthetic collagen, alginate or other biodegradable polymer or a biocompatible material such as polyurethane, polypropylene, silicone or natural rubber. The supporting and reinforcing fabric may be coated, impregnated or plates with materials such as silver, zinc, gold, platinum or carbon.

It is also possible to omit the supporting and reinforcing layer should the semipermeable membrane and the biodegradable tissue interface be made sufficiently strong to facilitate handling and if EMF therapy is not required.

It is also possible to omit the semipermeable membrane for situations like transcutaneous stimulation for pain relief.

In addition topical growth promoting, antibacterial or antiallergic agents such as silver sulphadiazene, zinc and other substances may be incorporated into the dressing, preferably into the collagen, alginate or collagen-alginate of the biodegradable tissue interface.

The advantages of the composite wound dressing according to the present invention include; control of the rate of water vapour transmission from the wound thereby presenting local dehydration, all processes in the wound healing phase are enhanced, e.g. inflammation is reduced, epithelialisation and collagen synthesis is increased, its layered structure gives it flexibility and mechanical strength and facilitates easy handling, the electrical conductivity of the supporting layer can be used to facilitate post-operative pain relief, and the dressing is self-sealing non-tissue adhesive, simply peeling off when required, when the dressing is used in the EMF assisted mode, the collagen synthesis phase of the wound healing is greatly enhanced thereby increasing the strength of the wound in the long term, and reduced scar formation and improved clinical appearance are an advantage of using this composite wound dressing.

Claims:

1. A composite wound dressing comprising in a layered arrangement, a semipermeable membrane, a supporting and reinforcing permeable layer, and a non-stick, self-sealing biodegradable tissue interface, said permeable layer being located between the semipermeable membrane and the biodegradable tissue interface.

2. A wound dressing as claimed in claim 1, wherein the supporting and reinforcing permeable layer is either an electrical insulator or an electrical conductor.

3. A wound dressing as claimed in claim 2, wherein the said permeable layer is a polyester, polyethylene, rayon or cotton fabric coated with carbon-doped silicon or natural rubber.

4. A wound dressing as claimed in claim 2, wherein the said permeable layer is a polyester, polyethylene, rayon or cotton fabric plated or deposited with metals such as silver, zinc, gold, platinum, carbon or coated with carbon-doped silicon or natural rubber.

5. A wound dressing as claimed in claim 2, wherein the said permeable layer is a charcoal cloth fabric.

6. A wound dressing as claimed in claim 5, wherein the said cloth fabric is produced by carbonising and activating a woven viscose rayon fabric in a temperature range of (700 - 1200)^{o}C.

7. A wound dressing as claimed in any preceding claim wherein the said tissue interface is a biodegradable polymer or synthetic collagen produced from animal sources.

8. A wound dressing as claimed in any one of claims 1-6, wherein the said biodegradable interface is a sodium-calcium alginate mixture with a ratio of (Na-Ca)=0.1 to 50 and it is produced from seaweed.

9. A wound dressing as claimed in any one of claims 1-6, wherein the said biodegradable interface is a collagen-alginate complex with a ratio of (Collagen/Alginate) = 0.1 to 30 and is

produced as a semipermeable film or an opened foamed structure.

10. A wound dressing as claimed in any preceding claims wherein the biodegradable tissue interface is treated (with methylglyoxal or alike) to increase electron spin density and electrical conductivity and dielectric dispersion.

11. A wound dressing as claimed in any preceding claim wherein the semipermeable membrane is a synthetic collagen.

12. A wound dressing as claimed in any one of claims 1-8 where the semipermeable membrane is an alginate or biocompatible polymer.

13. A wound dressing as claimed in any of the claims of the (1-11) where any one of the composite layer material is used as a temporary wound cover.

14. A composite wound dressing comprising in a layered arrangement, a semipermeable membrane and a biodegradable tissue interface.

15. A composite wound dressing comprising in a layered arrangement, a reinforcing and supporting permeable layer and biodegradable tissue interface.

16. A composite wound dressing comprising in a layered arrangement, a semipermeable membrane and an electrically conductive reinforcing and supporting permeable layer.

17. A permeable electrically conductive dressing as hereinbefore described with reference to Fig. (1, 2, 3, 4, 5) of the drawings.

18. A wound dressing substantially as hereinbefore described with reference to Fig. 1 or Fig. 2 or Fig. 3 or Fig. 4 or Fig. 5 of the drawings with or without incorporating growth promoting therapeutic antibacterial or anti-allergic agents for controlled topical therapy.

FIG. 1.

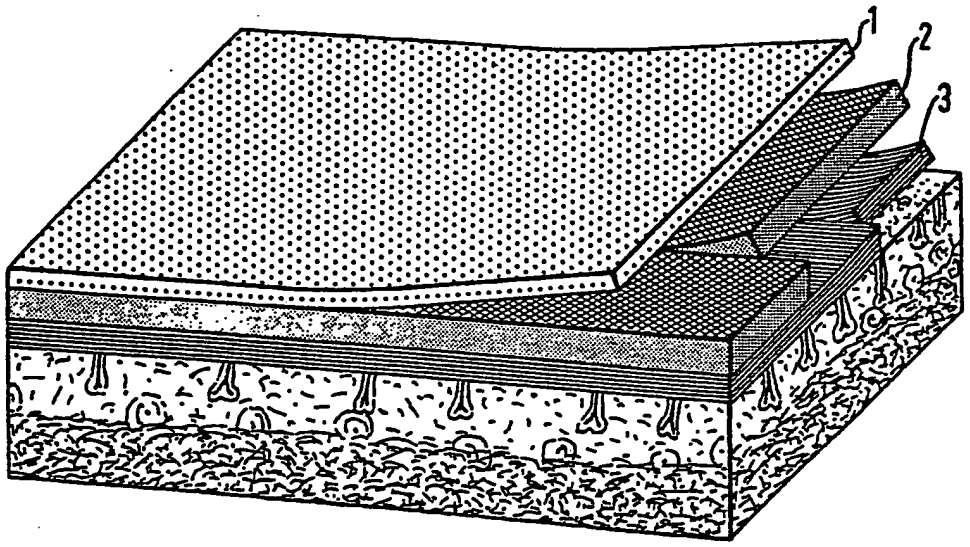


FIG. 2.

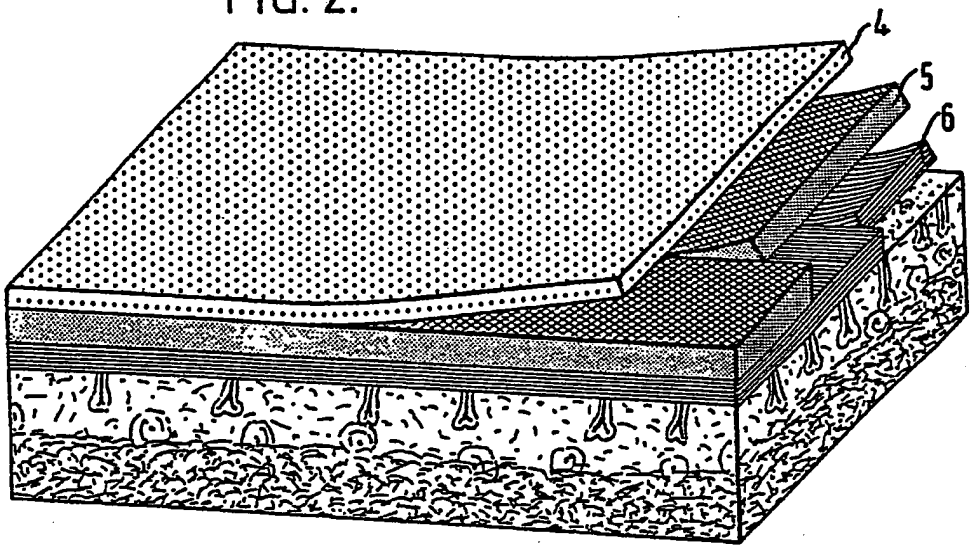


FIG. 3.

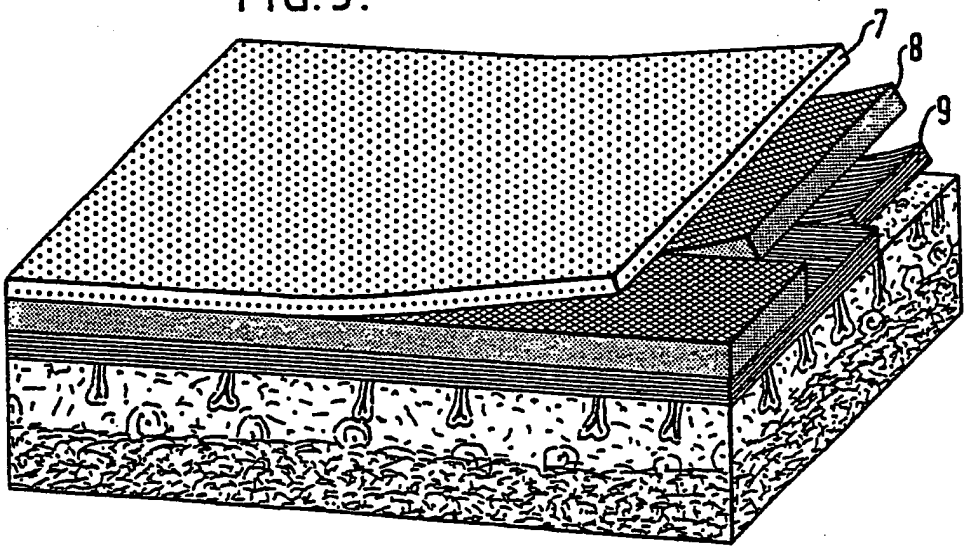


FIG. 4.

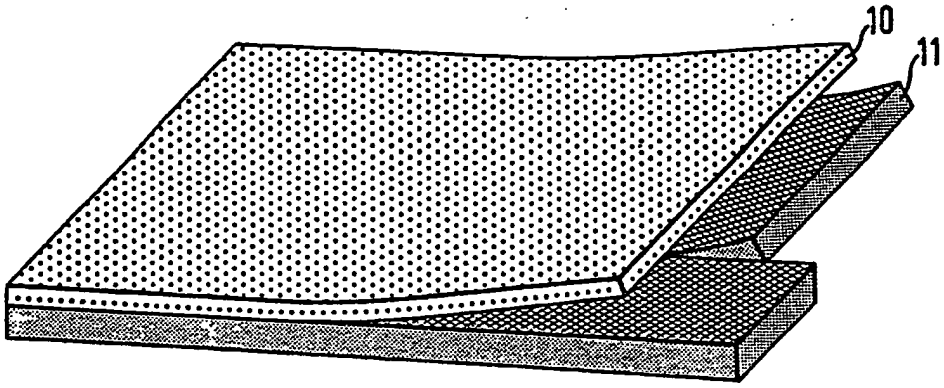


FIG. 5.